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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,411	10/16/2000	Norberto Festo	B-3992PCT618	7180

7590 08/22/2005

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EXAMINER

OH, TAYLOR V

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 08/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b>	<b>Application No.</b> 09/673,411	<b>Applicant(s)</b> FESTO, NORBERTO	
	<b>Examiner</b> Taylor Victor Oh	<b>Art Unit</b> 1625	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 12 July 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.  
 b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
 (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);  
 (b) ☐ They raise the issue of new matter (see NOTE below);  
 (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: see pages 2-5. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
 5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
 6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
 7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
 The status of the claim(s) is (or will be) as follows:  
 Claim(s) allowed: \_\_\_\_\_.  
 Claim(s) objected to: \_\_\_\_\_.  
 Claim(s) rejected: \_\_\_\_\_.  
 Claim(s) withdrawn from consideration: \_\_\_\_\_.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see pages 2-5.  
 12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). \_\_\_\_\_.  
 13. ☐ Other: \_\_\_\_\_.

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It is noted that applicants have filed an Amendment after the Final Rejection on 7/12/05; applicants' attorney has addressed the issues of record. The proposed amendment will NOT be entered ;and, it is not in a condition for allowance.

**The Status of Claims:**

Claims 1, 3-4,9,13-15,18-43, and 58 are pending.

Claims 22, and 24 have been rejected.

Claims 1, 3-4, 9,13-15, 18-21, 23, 25-30, 39, 40, and 43 have been objected.

Claims 31-38, 41-42, and 58 will be allowable.

**Claim Objections**

The objection of Claims 1, 9 ,and 43 can be overcome with the proposed modification in the amendment.

**Claim Rejections - 35 USC § 112**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of Claim 22 under 35 U.S.C. 112, second paragraph can be overcome with the proposed modification in the amendment. However, the rejection of

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Claim 24 under 35 U.S.C. 112, second paragraph has been maintained due to applicants' failure to modify the claim in the amendment.

Furthermore, there is still some issue to be resolved with claim 20.

In claim 20, the phrase " an enzymatic effect" is recited. This is vague and indefinite because the specification does not elaborate how the active ingredient has " an enzymatic effect". Therefore, an appropriate correction is required.

**The new issue**

The phrase " A pharmaceutical composition comprising, in addition to one or more pharmaceutically active ingredients " in claim 1 raises a new issue that would require further consideration and search.

**Applicants argue the following issues:**

- a. Claim 22 is amended to specify that the antineoplastic adjunct drug consists of folic acid replenishers, rather than includes them, thereby clarifying the composition of the antineoplastic adjunct drug.
- b. The expression "comprises " was replaced by the expression "is" in claim 24 in the prior art amendment ; therefore, there is an error on the basis for the rejection.

Applicants' arguments have been noted, but the arguments are not persuasive.

First, regarding the first argument, the Examiner has agreed that the proposed modification in the amendment can overcome the rejection.

Second, regarding the second argument, the Examiner has noted applicants' argument. However, the proposed amendment has still shown the word "comprises" in claim 24 unlike applicants' argument as shown below:

24. (As amended) A method as claimed in Claim 13, wherein the active ingredient is an anthelmintic that is effective against Cestodes, Nematodes, Onchocerca, Schistosoma, or Trematodes, or wherein the active ingredient comprises an antiprotozoal drug that is effective against Leshmania, Trichomonas, Trypanosma, or a combination thereof.

**Allowable Subject Matters Proposed by the Examiner**

In claims 1, 31, 32, and 58, the phrase "the one or more active ingredients" is recited. The specification has disclosed only five active ingredients in the topical formulations containing anti-inflammatory drugs: Ketoprofen, diclofenac Sodium, Ibuprofen, Etodolic Acid, and Piroxicam and the claimed PFPE compound, and etc. There are no other active ingredients which have been exemplified in order to show the workability of the various active ingredients present in the formulations. Therefore, the rejection based on the scope of enablement of the claimed invention under 35 U.S.C. 112, first paragraph, can be applied because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly

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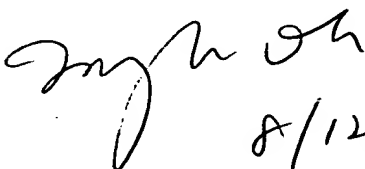
connected, other active ingredients unrelated to the currently claimed invention commensurate in scope with these claims.

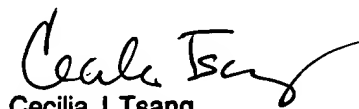
However, in order to expedite the prosecution of the case to be allowable, the examiner recommends to add the only five active ingredients into the claims 1, 31, 32, and 58 with the cancellation of the other active ingredients in the claims 20-22. Until the issues are resolved, the allowance of the application will be delayed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 571-272-0689. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
8/12/05

  
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